IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

GENPHARM INC., Plaintiff, v. PLIVA-LACHEMA a.s. and PLIVA d.d., Defendants.	Civil Action No. 03-CV-2835 Judge Arthur D. Spatt Magistrate Judge James Orenstein **FILED ELECTRONICALLY**

GENPHARM'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION AND ON FORUM *NON CONVENIENS* GROUNDS

Plaintiff Genpharm Inc. ("Genpharm") respectfully submits this memorandum of law in opposition to Defendants' (collectively, "Pliva") motion to dismiss for lack of subject matter jurisdiction and on forum *non conveniens* grounds.

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INTRODUCTION

Pliva's motion to dismiss for lack of subject matter jurisdiction and on forum *non conveniens* grounds is—like its prior motions—wholly without merit. *Pliva itself previously conceded there was subject matter jurisdiction here nearly 7 months ago.* (*See* D.E. # 40 at 1). Its sudden change of heart alone renders this motion suspect to stay the least. Nevertheless, by any standard, Genpharm has asserted a cognizable claim for breach of contract concerning the manufacture and sale of warfarin API under the United Nations Convention on Contracts for the International Sale of Goods, *reprinted in* 15 U.S.C. app. at 334-94 (1997 & Supp. 2003) ("CISG")—which Pliva does not deny is a "law" or "treaty" of the United States. Contrary to Pliva's repeated assertions, this dispute is all about Pliva's failure to manufacture and sell warfarin API to Genpharm for sale and use in the United States. Indeed, the entire contractual relationship between Pliva and Genpharm existed for no other reason than to provide Genpharm with an FDA-qualified source of warfarin API for the U.S. market. Such disputes lie at the very heart of the CISG. *See Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 201 F. Supp. 2d 236, 281 (S.D.N.Y. 2002) (holding that the CISG applies to agreements for the supply of API for the U.S. generic market). No more is required for denial of the motion.

Pliva's forum *non conveniens* arguments are equally baseless. As an initial matter, Pliva has waived this ground by waiting over a year to raise it without explanation, as Magistrate Judge Orenstein has already pointed out. That is reason enough to deny the motion. Moreover, such motions are the exception, not the rule, and it should make little difference that Genpharm does not reside here. *See Manela v. Garantia Banking Ltd.*, 940 F. Supp. 584, 592 (S.D.N.Y. 1996) (recognizing that "fact that plaintiff is not [itself] a resident of the United States . . . 'is not an invitation to accord [its] selection of an American forum no deference since dismissal for *forum non conveniens* is the exception rather than the rule'"). Indeed, such motions are routinely

denied where, as in this case, Pliva merely seeks to shift any inconvenience from itself to Genpharm.

For all these reasons, the motion should be denied in its entirety. In the alternative, the motion should be denied as premature until Genpharm has the opportunity to take full and fair discovery of these issues, as already ordered by Magistrate Judge Orenstein.

BACKGROUND

We assume familiarity with Genpharm's Amended Complaint (D.E. # 34), and focus here only on those facts most pertinent to this motion. "When addressing a motion to dismiss, the Court must accept the allegations of the complaint as true, and construe all reasonable inferences in favor of the plaintiff." *Meehan v. Patchogue-Medford Sch. Dist.*, 29 F. Supp. 2d 129, 132 (E.D.N.Y. 1998) (Spatt, J.) (citations omitted). Genpharm's well-pleaded allegations—that Pliva conveniently ignores and that warrant denial of Pliva's motion—are as follows.

The FDA approval process, and custom and practice in the pharmaceutical industry, for the sale of generic drugs in the United States.

Before marketing a generic drug in the United States, an applicant (like Genpharm here) must file an ANDA with FDA in which it identifies, *inter alia*, the company (like Pliva here) that will manufacture and supply the API used to make the generic drug product. (Am. Compl. ¶¶ 25-28.) The ANDA must also incorporate by reference that API Supplier's DMF (which describes where and how the API is made), which is also on file with FDA. (*Id.*) It is generally understood in the pharmaceutical industry that the API Supplier who allows its DMF to be referenced in an ANDA assumes the legal obligation to supply API to the generic manufacturer once the ANDA is approved. (*Id.* ¶ 33.) This widespread custom and understanding is borne, in part, by the fact that: (1) it is that supplier's DMF that FDA reviews and whose manufacturing procedures and facilities FDA subsequently approves; and (2) it is very onerous and time-

consuming for a generic manufacturer to qualify a new API Supplier with FDA. (*Id.*) Once FDA approves an API Supplier with respect to a particular drug product, the generic drug manufacturer may not use API from another supplier without FDA's prior approval, which can take many months, if not years, to obtain. (*Id.* ¶ 34.)

Genpharm contracts with Pliva for the manufacture and supply of warfarin API for use in Genpharm's generic warfarin product for the United States market.

This action for breach of contract arises out of Pliva's violation of binding agreements between the parties under which Pliva agreed to manufacture and supply Genpharm with warfarin API for use in the production of Genpharm's generic warfarin tablets for the U.S. market. (*See* Am. Compl. ¶¶ 35-66.) In December 1996, Pliva submitted a DMF to FDA stating its intent to manufacture warfarin API at its Pliva's Brno facility for sale to, and use by, generic drug manufacturers (like Genpharm) in the United States. (*Id.* ¶¶ 36-37; *see also* 6/17/04 Topinka Decl. Ex. D.) Shortly thereafter, Genpharm began the preliminary development work necessary to prepare and submit an ANDA to FDA for generic warfarin tablets for the U.S. market, which included obtaining a commercial source of warfarin API. (Am. Compl. ¶ 38.) To that end, in February 1997, Genpharm purchased its first developmental quantities of warfarin API from Pliva and began a close collaboration to qualify Pliva as Genpharm's sole supplier of warfarin API for the U.S. market. (*Id.* ¶¶ 39-40.) In a "Letter of Access" dated November 19, 1999, Pliva authorized FDA to use Pliva's DMF in support of any ANDA filed by Genpharm, thus acknowledging, *inter alia*, that Pliva would, subject to FDA's prior inspection and approval, manufacture warfarin API for Genpharm at its Brno facility. (*Id.* ¶¶ 41-44; *see also* 6/17/04 Topinka Decl. Ex. D.)

On May 23, 2000, in reliance on Pliva's DMF and agreement to supply warfarin API, Genpharm filed an ANDA seeking FDA approval to market warfarin sodium tablets in the

United States. (Am. Compl. ¶ 45.) That ANDA identified Pliva as Genpharm's sole supplier of warfarin API. (*Id.* ¶ 46.) In accordance with industry custom and practice, Pliva understood and agreed that, as Genpharm's exclusive API Supplier, Pliva was expected and obligated to supply Genpharm with warfarin API for the U.S. market upon ANDA approval. (*Id.* ¶ 47.) As such, in reliance on that binding supply relationship (and Pliva's repeated assurances that it would supply Genpharm with warfarin API), Genpharm and Pliva entered into a Manufacturer Agreement on February 13, 2001, under which Pliva became Genpharm's sole approved manufacturer of warfarin API to be manufactured according to Genpharm's product specifications at Pliva's Brno facility. (*Id.* ¶¶ 48-49.) To prevent delays in FDA approval and commercial marketing, the agreement, *inter alia*, required Pliva to notify and obtain approval from Genpharm before changing its warfarin manufacturing process or site. (*Id.* ¶¶ 48-53.)

Pliva's unilateral breach of contract and failure to supply warfarin API manufactured at its Brno facility.

By March 2002, except for a scheduled FDA inspection of Pliva's Brno facility, Genpharm was set to receive FDA approval of its ANDA in June 2002 and to begin commercial marketing in the United States. (Am. Compl. ¶¶ 52-54.) That same month, however, Pliva refused to allow an FDA inspection of its Brno facility, and further notified Genpharm that Pliva had unilaterally transferred, without Genpharm's approval, all warfarin API production for the U.S. market to another facility, thus delaying FDA approval indefinitely—*and leaving Genpharm without a source of supply*. (*Id.* ¶¶ 55-61; *see also* 6/17/04 Topinka Decl. Ex. M). To date, Genpharm's ANDA still isn't approved, and Pliva still hasn't supplied Genpharm with warfarin API qualified for the U.S. market. (Am. Compl. ¶¶ 62-66.)

Procedural History

As such, Genpharm initially sued Pliva for breach of contract under the CISG on June 6, 2003, on the ground that Pliva had breached the parties' binding supply agreement by, *inter alia*, unilaterally transferring its manufacturing facility and failing to supply Genpharm with warfarin API. (D.E. # 1, Compl. ¶¶ 19, 100) ("This action arises under . . . the [CISG] . . . ."). This claim is not, as Pliva suggests, based solely on the Manufacturer Agreement, but rather on the parties' binding supply relationship, as evidenced by the custom and dealings between the parties. (Am. Compl. ¶¶ 46-47, 100). Pliva moved to dismiss for lack of subject matter (*i.e.*, lack of diversity) and personal jurisdiction. (D.E. ## 25-29.) In lieu of a response, Genpharm properly filed an Amended Complaint "as a matter of course" under Rule 15(a), FED. R. CIV. P., to assert, with greater specificity, federal question jurisdiction under the CISG and additional facts supporting personal jurisdiction. (Am. Compl. ¶¶ 19-21.) Pliva then filed a supplemental memorandum, in which it *conceded* subject matter jurisdiction, but not personal jurisdiction. (D.E. ## 40-42.) Genpharm opposed the motion and sought jurisdictional discovery. (D.E. ## 50-51.)

Notwithstanding Pliva's first motion to dismiss, Magistrate Judge Lindsay entered a Pretrial Scheduling Order on May 24, 2004, setting a discovery deadline of December 10, 2004. (D.E. # 62.) Genpharm served merits and jurisdictional discovery shortly thereafter. (D.E. # 70, Exs. C-F.) Pliva then served the present motion to dismiss on June 21, 2004, arguing—for the first time and over a *year* since the initial Complaint was filed—that this case has nothing to do with the sale of goods and so does not arise under the CISG, and that this forum is suddenly inconvenient. Pliva also moved to stay discovery on July 9, 2004. (D.E. ## 70-71.) Newly-assigned Magistrate Judge Orenstein denied the motion to stay, and also ordered Pliva to respond to Genpharm's discovery requests by August 5, 2004, and to supplement those responses by August 23, 2004. (7/21/04 Order, D.E. # 77; 7/23/04 Order, D.E. # 79.) Genpharm only

received Pliva's written discovery responses on the date of service of this response, August 9, but to date, has still not received any documents.

ARGUMENT

I. This Court Has Subject Matter Jurisdiction Over Pliva.

While subject matter jurisdiction cannot technically be waived, the eleventh-hour timing of this argument by Pliva renders it suspect to say the least. As Magistrate Judge Orenstein aptly observed, Pliva "again fails to offer any credible explanation as to why the matter was not raised sooner." (D.E. # 77 at 7.) As such, this argument should be viewed "with caution," (*see id.*), and for good reason, because it has no basis in law or fact.

Pliva's entire argument is premised on the unfounded assertion that there is no subject or "federal question" under the CISG solely because the contracts at issue do not involve the "international sale of goods." (Pliva Mem. at 2.) Nothing could be further from the truth. Pliva has impermissibly ignored the well-pleaded allegations of Genpharm's Amended Complaint—which this Court must treat as true and view in a light most favorable to Genpharm—demonstrating that the foundation of Genpharm's claims is the binding supply agreement between Genpharm and Pliva for the manufacture and sale of warfarin API for the U.S. market. In other words, the heart of this case is undeniably the sale of an international good, namely, warfarin API. No more is required to confer federal question jurisdiction under the CISG. This Court should reject Pliva's transparent attempt to take a premature shot at the merits of this dispute by making its case—albeit an exceedingly weak one—for why Genpharm has no right to recover under the CISG. In doing so, Pliva also disingenuously clouds the issue by focusing in isolation on one provision of the Manufacturer Agreement, as well as extraneous documents having nothing to do with Genpharm's and Pliva's binding warfarin supply relationship.

A. Genpharm's well-pleaded complaint meets the liberal pleading requirements for subject matter jurisdiction.

As a threshold matter, 28 U.S.C. § 1331 (2004) provides for "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." Stated otherwise, this Court has subject matter jurisdiction over any action "arising under" federal law. *Kim v. Ashcroft*, No. 04 Civ. 1639(SAS), 2004 WL 1687201, at *2 (S.D.N.Y. July 27, 2004). Pliva does not dispute that the CISG constitutes a "law" or "treaty" of the United States under § 1331 and that the contracts at issue here are "between parties whose places of business are in different States." CISG Art. 1(1); Pliva Mem. at 4. Nor does Pliva dispute that the CISG "creates a private right of action" for the enforcement of international contractual rights. *Asante Techs., Inc. v. PMC-Sierra, Inc.*, 164 F. Supp. 2d 1142, 1147 (N.D. Cal. 2001) (holding that CISG applied to contract between manufacturer and supplier, raising federal question jurisdiction). Instead, after initially conceding subject matter jurisdiction, Pliva now makes the extraordinary argument that the agreements at issue here do not involve the "sale of goods" and therefore fall "outside the scope of the CISG." (Pliva Mem. at 2-5.) Pliva is not only sorely mistaken, but this argument prematurely addresses the merits of this dispute, and *not* whether there is subject matter jurisdiction to reach the merits in the first place, which there certainly is.

"'An action *arises under* a federal statute where the statute creates or is a necessary element of the cause of action or the plaintiff would prevail if the statute were construed one way and lose if it were construed another.'" *Kim*, 2004 WL 1687201, at *2 (emphasis added) (citation omitted); *see also Bell v. Hood*, 327 U.S. 678, 684-85 (1946) (finding jurisdiction where petitioners' right to recover "will be sustained if the Constitution and laws of the United States are given one construction and will be defeated if they are given another"); *Rodriguez v. Debuono*, 175 F.3d 227, 233 (2d Cir. 1999) (per curiam) (finding jurisdiction "since a

determination of whether the plaintiffs have stated a right for which there is a judicially enforceable remedy necessitates the interpretation of two federal statutes"), *rev'd on other grounds*, 197 F.3d 611 (2d Cir. 1999).

This standard is a "modest" one, allowing for subject matter jurisdiction "as long as a complaint states a colorable federal claim." *Rodriguez*, 175 F.3d at 233 (citations omitted), *cited in Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, No. 03 Civ.8254(DLC), 2004 WL 1259884, at *5 (S.D.N.Y. June 9, 2004). Indeed, it is well-established that a federal question claim should only be dismissed for lack of subject matter jurisdiction if it is "so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy . . . ." *Oneida Indian Nation of New York State v. County of Oneida, New York*, 414 U.S. 661, 666-67 (1974) (citations omitted); *see also Meehan*, 29 F. Supp. 2d at 132 (denying dismissal for lack of subject matter jurisdiction, which "is warranted only where the plaintiff's complaint is 'so completely devoid of merit as not to involve a federal controversy'").

This analysis, though, "is *not* equivalent . . . to an evaluation of the *merits* of a party's federal claim." *People v. Terry*, 45 F.3d 17, 22 (2d Cir. 1995) (emphasis added) (citations omitted). Rather, "the test is whether the 'cause of action alleged is so patently *without* merit as to justify . . . the court's dismissal for want of jurisdiction.'" *Id.* (citations omitted). In other words, a court must determine "whether a plaintiff has asserted a non-frivolous federal claim, *not whether [the plaintiff] will ultimately be able to obtain relief under the relevant statute*." *Vengurlekar v. HSBC Bank*, No. 03Civ.0243 (LTS) DFE, 2004 WL 856292, at *2 (S.D.N.Y. Apr. 20, 2004) (emphasis added) (citation omitted) (denying dismissal for lack of subject matter jurisdiction where plaintiffs had clearly "asserted claims pursuant to the statute that are neither

wholly insubstantial nor frivolous"). In fact, it is "[b]ecause of the more-than-occasional difficulties involved in parsing a claim alleging federal question jurisdiction to determine whether it fails to state a claim or fails to meet jurisdictional requirements, [that] the federal courts have followed a general practice of granting jurisdiction in most cases and dismissing for lack of subject matter jurisdiction only under *narrow circumstances*." *Well-Made Toy Mfg. Corp. v. Lotus Onda Indus. Co.*, No. 02 Civ. 1151 (CBM), 2003 WL 42001, at *6 (S.D.N.Y. Jan. 6, 2003) (emphasis added) (citation omitted) (finding that "[w]hile perhaps not a model of clarity, plaintiff's complaint suffices under the liberal pleading standard").

Accepting Genpharm's well-pleaded allegations as true and drawing all reasonable inferences in Genpham's favor, as this Court must, *see Meehan*, 29 F. Supp. 2d at 132, Genpharm has clearly satisfied the modest pleading requirements for subject matter jurisdiction under the CISG. Genpharm alleges that a legally binding supply relationship between Pliva and Genpharm arose under the CISG out of, among other things, custom and practice in the pharmaceutical industry; the usage and dealings between the parties; Pliva's representations, promises and actions; the Letter of Access to Pliva's DMF; the Manufacturer Agreement; and the Distributor Agreement. (*See, e.g.,* Am. Compl. ¶¶ 33-53.)

As discussed below, the CISG requirements are not formal and do not even require a written instrument. Under the CISG, "[a] contract may be proven by a document, oral representations, conduct, or some combination of the three." *Geneva Pharms.*, 201 F. Supp. 2d at 281 (citing CISG Art. 11); *see also* CISG Explanatory Note, Part One, Art. E ¶ 15 ("The Convention does not subject the contract of sale to any requirement as to form. In particular, article 11 provides that no written agreement is necessary for the conclusion of the contract."). A binding agreement can arise, as Genpharm alleges here, through a variety of conduct, including

"negotiations, ***any practices*** which the parties have established between themselves, ***usages*** and ***any subsequent conduct*** of the parties." CISG Art. 8(1), (3) (emphasis added). Genpharm further alleges that Pliva breached its binding supply obligations by, among other things, unilaterally moving its manufacturing facility and depriving Genpharm of a commercial source of warfarin API—thus, delaying Genpharm's ANDA approval and commercial marketing indefinitely. (*See* Am. Compl. ¶¶ 54-66, 100.)

No more is required to satisfy the liberal pleading requirements for subject matter jurisdiction. Genpharm's ultimate right to recover will be sustained depending on how this Court and/or the jury construe and apply the CISG to the facts of this case. But that is a question for another day, and should not be answered based on Pliva's conclusory assertions alone, without discovery. In the end, Pliva's argument that the CISG does not apply here puts the cart before the horse and is nothing more than a premature shot at the merits of this dispute. Just because there is a chance that Genpharm might not win based on Pliva's construction of the CISG, however, does not deprive this Court of jurisdiction to reach that question in the first place after full and fair discovery. Otherwise, every federal question case could be decided on a motion to dismiss for lack of jurisdiction. Accordingly, Genpharm asserts more than a "colorable" federal claim "arising under the Constitution, laws, or treaties of the United States" to withstand the minimal jurisdictional requirement.

B. This dispute is governed by the CISG.

There is also no question that the CISG applies to this dispute. The CISG is a self-executing agreement between the United States and other signatories that embodies a uniform set of rules for the creation and interpretation of, and the related obligations of parties to, international sales contracts. *See generally* CISG; *Delchi Carrier SpA v. Rotorex Corp.*, 71 F.3d 1024, 1027-28 (2d Cir. 1995); *Geneva Pharms.*, 201 F. Supp. 2d at 281. The contracting parties

to the CISG believed that "the adoption of uniform rules which govern contracts for the international sale of goods and take into account the different social, economic and legal systems would contribute to the removal of legal barriers in international trade and promote the development of international trade." CISG preamble. As such, "[i]n the interpretation of [the CISG], regard is to be had to its international character and to the need to promote uniformity in its application and the observance of good faith in international trade." CISG Art. 7(1). The Second Circuit has also instructed that courts must "look to [the] language [of the CISG] and to 'the general principles' upon which it is based" to otherwise determine the applicability of the CISG. *Delchi*, 71 F.3d at 1028.

1. The Manufacturer Agreement here alone is covered by the CISG.

First of all, contrary to Pliva's unsupported assertions (Pliva Mem. at 4-5), manufacturer agreements like the one at issue here are, in fact, covered by the CISG. As Pliva concedes, the CISG applies to contracts for the "sale" of goods. (*Id.* at 4.) In this connection, however, the CISG further provides that "[c]ontracts for the supply of goods to be *manufactured or produced are to be considered* ***sales*** unless the party who orders the goods undertakes to supply a substantial part of the materials necessary for such manufacture or production." CISG Art. 3(1) (emphasis added). As such, the Manufacturer Agreement clearly falls within the scope of the CISG. *See Asante Techs.*, 164 F. Supp. 2d at 1147 (holding that the CISG applies to a contract to supply goods between a manufacturer and supplier and supports federal question jurisdiction).

Moreover, to argue, as Pliva does here, that the Manufacturer Agreement does not involve the sale of a good, either directly or impliedly, is ludicrous and ignores reality. Indeed, the document itself lends no credence to this absurd theory. It is a contract, entitled "Manufacturer Agreement," entered into by and among the parties here, for the manufacture of a "Product," namely, warfarin API. The agreement also contains product "Specifications" and

"Certificates of Analysis" for the warfarin API that Pliva agreed to manufacture and supply to Genpharm. Unless Pliva expects this Court to believe that such specifications were provided for no reason at all, or that Pliva simply agreed to provide Genpharm with the unilateral power to control where Pliva's warfarin API is manufactured just for the fun of it, or perhaps that Pliva planned to give its warfarin API away for free, the Manufacturer Agreement is unequivocally a contract for the manufacture and sale of a good. Indeed, there was no other reason for Genpharm to have referenced Pliva's DMF in its ANDA, designated Pliva as its sole supplier of warfarin API, and entered into this Agreement in the first place unless Pliva had agreed to manufacture, and Genpharm agreed to purchase, Pliva's warfarin API.

Nor does it matter that the Manufacturer Agreement itself does not contain "price or quantity" terms, as Pliva asserts. (*See* Pliva Mem. at 4-5). Article 14 of the CISG, on which Pliva so heavily relies, does not suggest otherwise. Article 14, entitled "Formation of the contract," merely provides that "***[a] proposal*** for concluding a contract . . . ***constitutes an offer*** if it is sufficiently definite and indicates the intention of the offeror to be bound in case of acceptance. A proposal is sufficiently definite if it indicates the goods and expressly or implicitly fixes or makes provision for determining the quantity and the price." CISG Art. 14(1); *see also* CISG Art. 4 (stating that the CISG explicitly "governs only the ***formation of*** the contract of sale and the ***rights and obligations*** of the seller and the buyer arising from such a contract" (emphasis added)). Article 55 of the CISG further provides that "[w]here a contract has been validly concluded but does not expressly or implicitly fix or make provision for determining the price, the parties are considered . . . to have impliedly made reference to the price generally charged at the time of the conclusion of the contract for such goods sold . . . ."

In this case, the Manufacturer Agreement expressly identifies the goods at issue and implicitly makes provision for determining quantity and price based on the custom and dealing between the parties, which are also binding under the CISG whether in writing or not. As such, that the Manufacturer Agreement (or the Distributor Agreement or Letter of Access for that matter) may lack price or quantity terms is irrelevant to the Court's subject matter jurisdiction analysis here, which should focus solely on the liberal pleading standard set forth above. None of the authority cited by Pliva holds otherwise, or even remotely addresses a motion to dismiss for lack of federal question jurisdiction based on the CISG. *See, e.g., Helen Kaminski Pty. Ltd. v. Marketing Austl. Prods., Inc.*, No. M-47 (DLC), 1997 U.S. Dist. LEXIS 10630, at 7-8 (S.D.N.Y. 1997) (addressing the ***enforceability*** of the distributor agreement at issue); *Amco Ukrservice & Prompriladamco v. Am. Meter Co.*, No. 0-2638, 2004 U.S. Dist. LEXIS 5301, at *8-9 (E.D. Pa. Mar. 29, 2004) (addressing whether joint venture agreements are ***invalid*** under the CISG).

2. There is a binding supply agreement or relationship between the parties under the CISG.

Even if the Manufacturer Agreement alone were not covered by the CISG as Pliva suggests, this would not detract from the totality of Genpharm's well-pleaded allegations setting forth a binding warfarin supply agreement between the parties based on documents, custom and practice in the industry, oral representations, and dealings between the parties. Once again, the CISG provides that "[a] contract may be proven by a document, oral representations, conduct, or some combination of the three." *Geneva Pharms.*, 201 F. Supp. 2d at 281 (citing CISG Art. 11); *see also* CISG Explanatory Note, Part One, Art. E ¶ 15. So the Court's analysis should not merely focus on the actual written agreements at issue to the exclusion of all other conduct and dealings between the parties. To the contrary, the CISG further provides that:

> [f]or the purposes of this Convention statements made by and other conduct of a party are to be interpreted ***according to his intent*** where the other party knew or could not have been unaware what that intent was. . . . In determining the intent of a party or the understanding a reasonable person would have had, ***due consideration is to be given to all relevant circumstances*** of the case including the negotiations, ***any practices*** which the parties have established between themselves, ***usages*** and ***any subsequent conduct*** of the parties.

CISG Art. 8(1), (3) (emphasis added). A quick look at the relevant circumstances here, including the evidence submitted by Pliva in this case, fully supports application of, and liability under, the CISG.

In this connection, Pliva's own authority fully recognizes that by submitting its Letter of Access to FDA (6/17/04 Topinka Decl. Ex. D), which Pliva does not dispute, Pliva "commit[ed] to the FDA that it will manufacture its material as set forth in its DMF." *Geneva Pharms.*, 201 F. Supp. 2d at 246-47, *cited in* Pliva's Mem. at 3. Moreover, Pliva submits to this Court a "purchase confirmation," dated December 5, 2003, directed to Pliva-Lachema a.s., which explicitly sets forth that the relevant product is "Warfarin Sodium Clathrate – Quality ***according to requirements by Merck Generics,***" together with quantity and price terms. (6/17/04 Topinka Decl. Ex. L; *see also id.* Ex. B (Order for "12 kgs Warfarin Sodium Clathrate for Genpharm").) Genpharm has also alleged in detail a commercial collaboration between Genpharm and Pliva under which Pliva agreed to become Genpharm's sole supplier of warfarin API, which led to the Manufacturer and Distributor Agreements. (*See* Am. Compl. ¶¶ 35-66; *see also* 6/17/04 Topinka Decl. Exs. M (Letter in which Pliva states that "[w]e are confident that our business relations will develop to the benefit of both our companies"), T (Letter stating that "[t]he decision with respect to Warfarin Sodium Clathrate was made in a good faith with intention to ensure the launch of the high quality product in the US produced according to the GMP principles in facility that has a chance to pass the FDA inspection in the shortest possible time. Such solution would allow Merck and PLIVA to reach 'win-win' commercial solution."), Q (Letter stating that "[w]e have

been working on penetration of Warfarin SSC into American market . . . . All these activities, which mean a lot of work and also finances, are based on the long term agreement between Pliva-Lachema and AliaPharm and Manufacturer Agreement between Pliva Lachema and Genpharm")). Pliva simply ignores, and indeed conspicuously does not deny, the totality of Genpharm's allegations that establish a binding agreement to supply warfarin API under the CISG.

Instead, the best Pliva can do is point to a purported (and non-certified) English translation of a contract between Aliapharm and Pliva concerning the sale of warfarin API in the United States and Canada. (Pliva Mem. at 6-8; 6/17/04 Topinka Decl. Exs. G-I.) This contract, Pliva argues, allegedly precludes subject matter jurisdiction here because it prohibits Pliva from selling warfarin API directly to Genpharm without going through Aliapharm first. Wrong again. For starters, whatever this contract does as between Pliva and Aliapharm, it does not somehow erase or nullify the binding Manufacturer Agreement and warfarin supply relationship between Genpharm and Pliva under the CISG. And secondly, but perhaps more importantly, Pliva disingenuously omits the fact that, as fully alleged by Genpharm, Aliapharm was at all times acting as the agent and broker of, and at the direction of, Pliva for purposes of supplying and selling Pliva's warfarin API to Genpharm. (*See* Am. Compl. ¶¶ 51-61).

In sum, Pliva's new position, *i.e.*, that the contracts at issue here were not for the sale of goods and therefore do not fall within the scope of the CISG, is news to both Genpharm and FDA, both of which understood and expected that Genpharm would purchase, and Pliva would manufacture and supply, warfarin API to be used in Genpharm's U.S. generic warfarin product. Indeed, the only reason Genpharm and Pliva had any contractual relationship at all was for the

international purchase and sale of warfarin API (undeniably a "good") for generic warfarin tablets to be sold in the United States.

II. Dismissal Based On Forum *Non Conveniens* Is Inappropriate.

A. Pliva has waived its forum *non conveniens* argument.

Pliva's motion based on forum *non conveniens* is equally baseless and untimely. Unlike subject matter jurisdiction, it is well-settled that this defense may be waived if not brought within a reasonable time. *See, e.g., Cable News Network L.P. v. CNNews.com*, 177 F. Supp. 2d 506, 528 (E.D. Va. 2001) (recognizing that "[i]t is well-established that 'a [party] must assert a motion to dismiss for *forum non conveniens* within a reasonable time" and denying as untimely motion to dismiss on forum *non conveniens*), *vacated, in part, on other grounds,* No. 02-1112, 2003 WL 152846 (4th Cir. Jan. 23, 2003); *Ori, Inc. v. Lanewala*, No. 99-2402-JWL, 2000 WL 1683659, at *2-3 (D. Kan. Nov. 3, 2000) (same). Even the authority on which Pliva relies supports this well-established rule of law. *See, e.g., Chateau Des Charmes Wines Ltd. v. Sabata USA, Inc.*, No. C-01-4203 MMC, 2003 U.S. Dist. LEXIS 20337, at *9 (N.D. Cal. Nov. 10, 2003) (recognizing that "a defendant must assert a motion to dismiss for forum non conveniens ***within a reasonable time*** after the facts or circumstances which serve as the basis for the motion have developed and become known or reasonably knowable to the defendant" (emphasis added)). And in fact, Magistrate Judge Orenstein also recognized that, given the timing, Pliva's most recent motions should be viewed "with caution." (*See* D.E. # 77 at 7 (further recognizing that while "Pliva explains why, in its view, its *forum non conveniens* defense is not time-barred, [it] does not explain why it was so late in being asserted").)

Pliva's motion should be denied as untimely. The purported bases underlying this motion relate to Pliva's contention that, among other things, "the events, contracts, and discussions that underlie this action all took place abroad, and all of the relevant witnesses and documents are

similarly located abroad." (Pliva Mem. at 8.) But these are not facts that suddenly became known to Pliva over a year after this action was filed. Quite the contrary, Genpharm never modified any of the substantive allegations to this action, *i.e.*, documents governing and breaches by Pliva, which would have altered what documents or witnesses are otherwise key to this case. (*Compare* D.E. # 1 *with* D.E. # 34.) Even Pliva concedes, as it must, that the "Amended Complaint is virtually identical to the original Complaint." (D.E. # 40 at 1.) Nor does the fact that Pliva may have recently obtained new counsel (Pliva Mem. at 4) justify Pliva's delay in bringing its forum *non conveniens* motion, where the action has been pending for over a year (D.E. # 1), and Genpharm's Amended Complaint has been pending since mid-December (D.E. # 34)—or nearly 8 months.

As Magistrate Judge Orenstein acknowledged, Pliva "clearly waited longer than might have been expected to notify the court . . . that the forum in which the parties have by now litigated for over a year is not convenient." (D.E. # 77 at 7). Such unexplained and unjustified delays are fatal to Pliva's motion, which should be denied for this reason alone. *See, e.g., Ori, Inc.*, 2000 WL 1683659, at *3 (denying as untimely defendant's forum *non conveniens* motion where "facts that defendant 'resides in India [and] was employed in India,' and that 'most of the witnesses are in India,' [were] not facts that have unexpectedly arisen in recent months").

B. This is otherwise an appropriate forum.

This Court "should begin with the assumption that the plaintiff's choice of forum will stand unless the defendant meets the burden of demonstrating . . . that trial in the chosen forum would be unnecessarily burdensome for the defendant or the court . . . ." *Iragorri v. United Techs. Corp.*, 274 F.3d 65, 71 (2d Cir. 2001) (citation omitted) (vacating dismissal of motion based on forum *non conveniens* grounds), *vacated, in part, on other grounds*, 314 F. Supp. 2d 110 (D. Conn. 2004). "The fact that plaintiff is not himself a resident of the United States, while

reducing the weight given to his choice of forum, 'is not an invitation to accord [its] selection of an American forum no deference since dismissal for *forum non conveniens* is the exception rather than the rule.'" *Manela*, 940 F. Supp. at 592 (citations omitted) (concluding that dismissal on forum *non conveniens* grounds was unwarranted); *see also R. Maganlal & Co. v. M.G. Chem. Co.*, 942 F.2d 164, 168 (2d Cir. 1991) (same). "Accordingly, since a foreign plaintiff's choice of forum is entitled to some weight, a defendant must still show that the balance of convenience sufficiently favors trial in the foreign forum to overcome the presumption in favor of plaintiff's choice." *R. Maganlal & Co.*, 942 F.2d at 168.

In assessing a forum *non conveniens* motion, a court will apply a two-prong test. "First it must determine whether an adequate alternative forum exists in which the case may be heard. 'Assuming there is such a forum, the Court must then balance a series of private and public interests in determining whether to retain the case or dismiss it in favor of [the] alternative forum.'" *Manela*, 940 F. Supp. at 590 (citations omitted). The defendant bears the burden of clearly establishing each factor, and demonstrating that "the balance of convenience tilts strongly in favor of trial in the foreign forum." *R. Maganlal & Co.*, 942 F.2d at 167. Pliva's skeletal two-page argument (Pliva Mem. at 14-15) falls well short of meeting this heavy burden.

1. Pliva fails to demonstrate an adequate alternative forum.

In determining whether an adequate forum exists, this Court must analyze whether "(1) the defendants are subject to service of process there; and (2) the forum permits 'litigation of the subject matter of the dispute.'" *Alnwick v. European Micro Holdings, Inc.*, 281 F. Supp. 2d 629, 647 (E.D.N.Y. Sept. 15, 2003) (Spatt, J.) (citation omitted) (denying motion to dismiss based on forum *non conveniens* grounds). Pliva does not even begin to address how the Czech Republic would be a suitable alternative forum for this dispute. Pliva merely asserts in conclusory fashion that "[t]here is no question that the Defendants would be amenable to process in the Czech

Republic, and that the Czech Republic is a suitable alternative forum" for this suit. (Pliva Mem. at 15.) But Pliva does not explain how Pliva d.d., a Croatian company, would "without question" be amenable to service of process in the Czech Republic; discuss the availability of contract claims or the discovery process in the Czech Republic; or otherwise provide any description of litigation and the enforcement of contractual rights in the Czech Republic.

Moreover, Pliva's present assertion that the Czech Republic is the most convenient forum is puzzling to say the least where, as here, Pliva previously argued that "*every key witness and the mass of relevant documents are located either in the Czech Republic, Croatia, Germany[,] the United Kingdom, or Canada.*" (D.E. # 71 at 8 (emphasis added)). How the Czech Republic winds up being the "most convenient" or suitable forum in these circumstances Pliva does not say—though one can hazard a guess that it would be "most convenient" for Pliva at least. That is simply not good enough. But even if it was, "[a] defendant does not carry the day simply by showing the existence of an adequate alternative forum." *Iragorri*, 274 F.3d at 74. Rather, "[t]he action should be dismissed only if the chosen forum is shown to be genuinely inconvenient and the selected forum significantly preferable." *Id.* at 74-75.

2. The balance applicable factors weigh heavily in favor of this Court.

If the Court determines that an adequate alternative forum exists, it must then "weigh the private and public interest factors to decide which forum . . . is more convenient and serves the interests of justice." *Alnwick*, 281 F. Supp. 2d at 647 (citation omitted). The private factors include: (1) the relative ease of access to evidence; (2) the availability of compulsory process for attendance of unwilling witnesses; (3) the cost to transport witnesses to trial; and, (4) other factors that make the trial ore expeditious or less expensive; whereas the public factors are: (1) settling local disputes in a local forum; (2) avoiding the difficulties of applying foreign law; (3) and, avoiding the burden on jurors by having them decide cases that have no impact on their

community. *Id.* (citations omitted). "No single factor . . . is dispositive, nor even entitled to 'central emphasis.'" *Manela*, 940 F. Supp. at 593 n.17 (citation omitted). "The Second Circuit has repeatedly noted[,] . . . a defendant must clear a very high hurdle to demonstrate that the aggregate of relevant factors warrant dismissal." *Dagen v. CFC Group Holdings, Ltd.*, No. 00Civ.5682(DAB)(THK), 2003 WL 194208, at *4 (S.D.N.Y. Jan. 28, 2003) (citations omitted); *see also Manela*, 940 F. Supp. at 591 (finding that "the burden at this stage of the analysis is on the movant to show that the balance of convenience tips 'strongly' in favor of dismissal"). Pliva cannot satisfy this "high hurdle" here.

a. The private interest factors weigh in favor of Genpharm's choice of forum.

Pliva argues only that "[l]ittle discovery has occurred, and Defendants have moved to stay discovery pending a determination on this motion," and further that the "documents and witnesses are located abroad." (Pliva Mem. at 15.) This bootstrapping argument should be dismissed out of hand where, as here, Pliva alone is responsible for the discovery delays and the fact that "[l]ittle discovery has occurred." Genpharm has attempted to move this case forward only to be stymied by Pliva's incessant, and indeed weekly, requests for stays of discovery. Magistrate Judge Orenstein finally denied Pliva's motion to stay and ordered Pliva to produce discovery responses by August 5, 2004, and supplement those responses by August 23, 2004. (D.E. # 77.) In fact, in his Order denying Pliva's motion to stay, he rightly concluded "[t]hat process will be inconvenient to some of the participants regardless of the location of the forum: as Pliva itself notes, 'every key witness and the mass of relevant documents are located either in the Czech Republic, Croatia, Germany[,] the United Kingdom, or Canada.'" (D.E. # 77 at 7.) In these circumstances, Pliva cannot, as a matter of law, meet its burden of establishing that the private interest factors favor one forum over another.

Magistrate Judge Orenstein further recognized that this case involves "a relatively straightforward breach of contract claim that would require relatively straightforward discovery . . ." (D.E. # 77 at 6.) And because the number of relevant documents should be small, the number of witnesses should likewise be small. These are all important considerations for this Court. *See, e.g., Manela*, 940 F. Supp. at 593-94 (finding that where the number of witnesses and documents is small and the majority of the documents is in English, the interest factors weigh in favor of the plaintiff and against dismissal); *ESI, Inc. v. Coastal Power Prod. Co.*, 995 F. Supp. 419, 426-27 (S.D.N.Y. 1998) (finding presumption of plaintiff's forum where, among other things, "the documents most relevant to ESI's claims . . . are either located in the United States or, as evidenced by attachments to the parties' motion papers, can be easily obtained" and the "documents were executed in English or have already been translated into English"). Further, Pliva has not claimed, much less established, that the testimony of any potentially critical witness will be unavailable in this forum or that witnesses wouldn't still incur traveling costs regardless of the final forum chosen. *See ESI, Inc.*, 995 F. Supp. at 427 (recognizing that "[w]hether this case proceeds in New York or El Salvador, witnesses would be required to travel internationally").

In the end, by blindly pointing to the Czech Republic, Pliva merely seeks to shift any potential inconvenience or burden from itself to Genpharm. But "[c]ourts generally refuse to dismiss cases for forum non conveniens in such situations." *Teevee Toons, Inc. v. Gerhard Schubert GMBH*, No. 00 Civ. 5189(RCC), 2002 WL 498627, at *8 (S.D.N.Y. Mar. 29, 2002) (citations omitted) (denying motion to dismiss for forum *non conveniens* where dismissal would shift inconveniences complained of by the defendant to the plaintiff); *see also ESI, Inc.*, 995 F.

Supp. at 429 (refusing to dismiss where litigation would impose burdens on both parties whether the case was tried in New York or abroad). So, too, should this Court.

b. The public interest factors likewise weigh in favor of Genpharm's choice of forum.

Pliva's contacts with this forum present important public concerns that weigh heavily in favor of adjudication in this forum. *See Manela*, 940 F. Supp. at 595 (recognizing that the foreign court "might well regard this dispute as having connections to the United States that are as substantial as any connections that it may have to Brazil"). Pliva initially told this Court that it had no contacts with, and derived no income from, this forum, when in reality the United States is Pliva's largest pharmaceutical market, and Pliva derives hundreds of millions of dollars from its licensing contracts with companies in this District. (*See, e.g.*, D.E. # 70, Ex. G at 6, 18). Even the recent documents attached to Pliva's second motion reveal heretofore unknown customers and contacts in this forum. (*See, e.g.*, 6/17/04 Topinka Decl. Ex. I).

The gravamen of this dispute also focuses on the United States. Genpharm applied to FDA to market lower-priced generic warfarin tablets in the United States and in this District using warfarin API from Pliva, which committed to FDA that it would produce the API necessary for Genpharm to produce its generic drug product. Now in light of Pliva's breaches, not only is FDA approval of Genpharm's generic warfarin indefinitely delayed, but American consumers are further deprived access to more affordable generic drugs. There could not be a more obvious local and national interest. Because of these interests, there shouldn't be a concern of burdening citizens in an unrelated forum with jury duty. *See ESI, Inc.*, 995 F. Supp. at 428 (concluding that "[b]ecause New York has a legitimate interest in this litigation, this factor [of burdening citizens with jury duty] is not implicated"). The Czech Republic can lay no greater claim to the subject matter of this dispute.

Finally, there should be minimal, if any, administrative difficulties arising from court congestion. Pliva has not addressed, much less demonstrated, that litigation in the Czech Republic or any other forum for that matter will proceed substantially more swiftly than in this District. To the contrary, a Pretrial Scheduling Order is already in place; Pliva has been ordered to produce discovery; and "this Court is already familiar with the general factual background and legal issues presented by this case." *Id.*

III. Dismissal Is Inappropriate Absent Discovery.

Should this Court determine that Pliva's motion has any merit whatsoever (and it shouldn't), the motion should still be denied as premature until Genpharm can take full and fair discovery on these issues. Indeed, Magistrate Judge Orenstein denied Pliva's motion to stay for this very reason. As Magistrate Judge Orenstein determined, "the reasons Pliva offers for dismissal are not . . . 'purely questions of law' involving 'no factual issues in need of further immediate exploration.'" (D.E. # 77 at 4.) Rather, "it is plain that the challenge to subject matter jurisdiction raises 'factual issues in need of further immediate exploration.'" (*Id.* at 5 (citing *Hachette Distrib., Inc. v. Hudson County News Co.*, 136 F.R.D. 356, 358 (E.D.N.Y. 1991) (Spatt, J.)); *see also Winston & Strawn v. Dong Won Sec. Co.*, No. 02 Civ. 0183 (RWS), 2002 WL 31444625, at *5 (S.D.N.Y. Nov. 1, 2002) (recognizing that "[a] court may allow discovery to aid in determining whether it has . . . ***subject matter jurisdiction***" (emphasis added)).

Magistrate Judge Orenstein similarly concluded that discovery was appropriate on the forum *non conveniens* issues, finding that "[t]his prong of Pliva's dismissal motion . . . is not purely a question of law." D.E. # 77 at 6; *see also Norex Petroleum Ltd. v. Access Indus., Inc.*, No. 02Civ.1499(LTS)(KNF), 2003 WL 1484269, at *2 (S.D.N.Y. Mar. 21, 2003) (finding that plaintiff was entitled to limited discovery in connection with forum *non conveniens* motion); *Base Metal Trading S.A. v. Aluminum*, No. 00 CIV.9627 JGK FM, 2002 WL 987257, at *3

(S.D.N.Y. May 14, 2002) (same). And it is undisputed that Genpharm is also entitled to discovery on personal jurisdiction issues, which form the basis of Pliva's first motion to dismiss. *See In re: Horizon Cruises Litig.*, No. 94 CIV. 5270(LMM), 1997 WL 762129, at *1 (S.D.N.Y. Dec. 10, 1997) (finding that trial court "was well within [its] considerable discretion . . . in granting jurisdictional discovery"); *see also W. Afr. Trading & Shipping Co. v. London Int'l Group*, 968 F. Supp. 996, 1001 (D.N.J. 1997) (concluding that "plaintiffs request for jurisdictional discovery is critical to the determination of whether we may exercise personal jurisdiction over the defendant"). At a minimum, then, before any dismissal, Genpharm would be entitled to complete discovery on each of the bases underlying Pliva's pending motions to dismiss as reinforced by Magistrate Judge Orenstein's July 21, 2004 Order.

CONCLUSION

For all these reasons, Pliva's second motion to dismiss should be denied in its entirety.

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Respectfully submitted,

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